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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1617	8

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/014,488	Applicant(s) CLAYTON, PAUL	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-33 are presented for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (WO 98/33494) of record in view of Gilles et al.(U.S.Patent No. 6,248,375B1) of record and further in view of Arbiser (US Publication 2001/0025034A1).

Kosbab on the abstract, page 2, lines 10-35, page 3, lines 25-30, page 4, line 23-page18, page 47-51 teaches a composition comprising active agents and their dosage amounts set forth in claims 1,6,11,13,17,22 and 29 for nutrient and therapeutic composition use for disease conditions associated with diabetes.

Kosbab also teach the above composition comprising biotin, omega-6 fatty acids (linoleic acid) and angiogenesis inhibitor. (page 13, line 12, page 14, line 4, page 33, lines 19-25, page 41, line 2).

Kosbab on page 4, lines 5-20 teaches that the nutrient composition can be combined with components that regulate glucose or insulin level and the use of functionally similar components which are structurally distinct or derived from different sources allows the inclusion of sufficiently high levels of total material to achieve a desired level of activity while avoiding the potential toxic effect that may result from use of high levels of any single component.

Gilles et al. on the abstract, column 10, lines 52-69, column 22, claim 11 and 12, column 10, lines 20-25, teach a nutritional composition for treatment of diabetes comprising FOS and other vitamins and minerals set forth in Applicant's claims 1,6,11,13,17,22 and 29.

Gilles et al. on column 10, lines 20-50 teach that FOS is readily available and it is preferential energy source to beneficial bacteria but against potential pathogens in the nutritional composition.

Arbiser teaches that curcuminoid inhibits angiogenesis. (title).

The difference between primary reference and Applicant's claimed invention is absence of FOS and insulin and specific angiogenesis inhibitor (curcuminoid) and specific dosage range set forth in claims 1,6,11,17,22 and 29. However, one of ordinary skill in the art would be motivated to employ FOS and insulin in view of Gilles et al. since Gilles et al. teach that FOS in diabetic composition is preferential energy source to beneficial bacteria in the diabetic nutritional composition. Furthermore, Kosbab taught that any of the components that regulate glucose or insulin level can be combined with

Kosbab's composition. Therefore, the skilled artisan would be motivated to combine well-known insulin (component that regulates glucose or insulin level, column 1, lines 22-25, Gilles et al.) and any other active agents taught by Gilles's composition including FOS to Kosbab's composition with reasonable expectation of success in formulating a diabetic nutritional formulation since the use of functionally similar components which are structurally distinct or derived from different sources allows the inclusion of sufficiently high levels of total material to achieve a desired level of activity while avoiding the potential toxic effect that may result from use of high levels of any single component. Further, it would have been obvious to employ curcuminoid in above combined teachings because Arbiser teaches that curcuminoid inhibits angiogenesis. One of ordinary skill in the art would have been motivated to employ curcuminoid into above combined teachings because Gilles teach that angiogenesis inhibitor is generally combined with diabetic composition taught by Gilles. One would have been motivated to combine these references and make such modification because they are drawn to same technical fields (constituted with same active ingredient and well known vitamins and minerals routinely incorporated in diabetic nutritional supplement) and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

The amounts of active agents to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant, and process of making are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and the

broad range of usual amounts are taught by Kosbab and represent conventional formulations and modes of administration.

It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants teaching.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicant's arguments filed February 21, 2003 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the references because the claimed invention recited specific dosages that can vary no more than 15% (w/w) above or below the specified amount. It is the Examiner's position that Kosbab reference teaches broad dosages, which encompasses Applicant's claiming dosage, and that Applicant has not provided any data showing surprising or unexpected result using the claiming invention of specific ranges broadly taught by the prior art. Applicant further argues that Kosbab describes nutrient and therapeutic formulation that contain form four to about fifty components in extremely broad dosage ranges and the dosage range of beta-carotene is 1-300mg. The Examiner's position is

that Applicant's composition comprising "at least the following compounds" like the prior art composition is also extremely broad and again, that Applicant's specific dosage range of beta-carotene falls within the range taught by the prior art. Applicant argues that Gilles described bagels, biscuits, cookies and other solid good containing an alternative source of carbohydrates and the baked goods are present in much lower amounts of vitamins and minerals found in the claimed invention. However, the Examiner's position is that the vitamins and minerals utilized in Gilles reference is also taught by the Kosbab with recommended dosage utilized which encompass Applicant's claiming range. Applicant further argues that there is no motivation to combine the medicinal formulations described by Kosabab with the bagels, biscuits, and cookies as described by Gilles and they have completely different utilities. The examiner's position is that Kosbab teaches the nutrient compositions for diabetics in general (page2, line 1, line 18) and Gilles et al. teaches nutritional bar designed for the diabetics (abstract, column 4, lines 59-62), therefore the utility of these two references are related. Applicant argues that it may be undesirable to add carbohydrate source to medicines and that Kosbab does not describe a carbohydrate source for use in his therapeutic and nutritional compounds and only carbohydrate source mentioned is e.g. honey. The Examiner's position is that Gilles et al. utilizes fructose as a source of carbohydrate and that fructose is found naturally in honey (column 5, lines 65-67, column 6, lines 63-65) and that fructose is also known to stimulate insulin production. Therefore it would be proper to combine both references of Kosbab and Gilles et al. Applicant argues that several other active agents required by the claimed invention are missing (e.g. omega 6 fatty acid, biotin and curcuminoids). This argument is addressed clearly in the above Action. Applicant argues that Kosbab actually teaches away from the use of niacin (or nicotinamide) in

his diabetic formulation. The Examiner's position is that Gilles teaches that niacin is compatible as diabetic nutritional composition and can be combined with other vitamins and minerals taught by Gilles which is also taught by Kosabab. It is well known that chromium complexes with niacin to helps insulin metabolize fat and convert food into energy. (see U.S.Patent No. 5,480,657, column 7-8) . Therefore, one would be motivated to combine niacin into Kosbab formulation to achieve benefit in diabetic patients in insulin bioavailablity. Applicant argues that there is simply no teaching for suggestion in the prior art to add insulin to the formulation. The Examiner's position is that Kosbab does teach that the nutrient components can be combined with components that regulate glucose or insulin levels. These teachings clearly suggest any component that regulates glucose or insulin levels (e.g. insulin) can be combined with above nutrient component. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Communication

It is requested to furnish Form PTO-1449 accompanied by pertinent references since Applicant's Information Disclosure Statement appears to be missing in the file.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Jennifer Kim
Patent Examiner
Art Unit 1617

jmk
May 19, 2003